

REMARKS

The present application is a divisional application of US Patent Application No. 09/799,317, now issued US Patent No. 6,613,801.

The following remarks are submitted to address the issues raised in the Office Action mailed July 28, 2005.

The status of the claims is as follows:

Claims 3-10, 16-28, 31, and 34-51 have been canceled.

Claims 1-2, 11-15, 29-30, and 32-33 are pending in the present application.

Claims 1, 2, and 11-15 stand allowed.

Claims 29, 30, 32, and 33 stand rejected under 35 U.S.C. § 112, first paragraph, as failing to comply with the written description requirement and the enablement requirement.

Claims 29 and 30 stand rejected under 35 U.S.C. § 112, second paragraph, as being indefinite.

The specification is objected because of informalities: Data is missing from page 44, [0084].

The Examiner has requested an update of the cross-reference section of the present application.

The Examiner has stated that the declaration is defective for failing to properly identify the application with which it is associated. A supplemental declaration under 37 C.F.R. § 1.67(a) is required by the Examiner.

Consideration of the pending claims and passage to allowance is respectfully requested in view of the previous amendments and following remarks.

Claim Amendments

In the interest of expediting allowance of the present application and without prejudice to re-entry of the claims 29, 30, 32, and 33, these claims have been canceled.

Claims 29; 30, 32 and 33 - 35 U.S.C. § 112

Claims 29, 30, 32, and 33 stand rejected under 35 U.S.C. § 112, first paragraph, and claims 29 and 30 stand rejected under 35 U.S.C. § 112, second paragraph, as being indefinite.

In the interest of expediting allowance of the present application and without prejudice to re-entry of the claims 29, 30, 32, and 33, Applicants have canceled these claims. Accordingly, the rejection of claims 29, 30, 32, and 33 is moot.

Specification

The specification is objected to because of informalities: Data is missing from page 44, [0084]. Applicants have amended the specification to include the missing data

The Examiner has requested an update of the cross-reference section of the present application. Applicants have amended the statement of related applications in [0001] to indicate that Application No. 09/799,317 is now US Patent 6,613,801.

Declaration

I. Background

In the Office Actions mailed July 25, 2005, and January 1, 2005, the Examiner stated that the originally filed declaration ("Original Declaration") in the present application is defective because "the specification to which the . . . declaration is

directed has not been adequately identified" as directed by 37 C.F.R. 1.63(b)(1). The Examiner stated that a supplemental declaration in compliance with 37 C.F.R. § 1.67(a) identifying the present application by application number and filing date is required.

The inaccurate information in the Original Declaration is the application number of the provisional application from which the present application claims the benefit of priority. In the Original Declaration, the incorrect priority application number is 60/346,125. The correct priority application number is 60/207,343, as recited in the amended Statement of Related Applications, which was filed at the same time as the Original Declaration.

On April 11, 2005, Applicants filed a petition under 37 C.F.R. § 1.183 requesting suspension of the rules because one of the named inventors is deceased. Applicants included with the petition a copy of the death certificate and a supplemental declaration executed by all of the other inventors. The supplemental declaration corrected the inaccurate domestic priority information identified by the Examiner in the Original Declaration and updated the mailing addresses of two of the inventors (Wysong and Patron). On July 11, 2005, Applicants' petition was denied.

Without conceding to any of the conclusions in the decision on Applicants' petition or waiving the right to file a renewed petition within the statutory period, Applicants submit that the Original Declaration is not defective and that the Original Declaration complies with § 1.63(b)(1) in that it sufficiently identifies the application to which it is directed.

Applicants respectfully request that the Examiner withdraw the requirement to file a supplemental declaration.

Further, Applicants submit that the inaccurate domestic priority information in the Original Declaration can be corrected by a supplemental application data sheet, which is included herewith.

II. Original Declaration Is Not Defective

The Original Declaration filed in the present application complies with the rules under § 1.63 and, specifically, in the information required by § 1.63(b)(1). Further, domestic priority information is not required by § 1.63. Therefore, Applicants respectfully submit that the Original Declaration is not defective.

A) The Original Declaration Complies with 37 C.F.R. § 1.63(a)-(d)

Under § 1.63(d)(1), a newly executed declaration is not required in a continuation or divisional application provided that :

- (i) The prior nonprovisional application contained an oath or declaration as prescribed by paragraphs (a) through (c) of this section;
- (ii) The continuation or divisional application was filed by all or by fewer than all of the inventors named in the prior application;
- (iii) The specification and drawings filed in the continuation or divisional application contain no matter that would have been new matter in the prior application; and
- (iv) A copy of the executed oath or declaration filed in the prior application, showing the signature or an indication thereon that it was signed, is submitted for the continuation or divisional application.

The present application (10/611,741) is a divisional application of application number 09/799,317, now US Patent 6,613,801. The Original Declaration filed in the present application is a copy of the declaration in 09/799,317, and it complies with each subparagraph in § 1.63(d)(1): (i) the prior application (09/799,317) contained a declaration as required by § 1.63(a)-(c); (ii) the present divisional application was filed by all of the inventors named in the prior application; (iii) no new matter is

contained in the present application relative to the prior application; and (iv) a copy of the declaration in the prior application was submitted for the present application.

Because the present application was not filed with an application data sheet, under § 1.63(a)-(c), a valid declaration must:

- (1) Be executed in accordance with § 1.68 which states that the declarant must be on the same document, warned that willful false statements and the like are punishable by fine or imprisonment, or both (18 U.S.C. § 1001) and may jeopardize the validity of the application or any patent issuing thereon. The declarant must also set forth in the body of the declaration that all statements made of the declarant's own knowledge are true and that all statements made on information and belief are believed to be true;
- (2) Identify each inventor by full name, including the family name, and at least one given name without abbreviation together with any other given name or initial;
- (3) Identify the country of citizenship of each inventor;
- (4) State that the person making the oath or declaration believes the named inventor or inventors to be the original and first inventor or inventors of the subject matter which is claimed and for which a patent is sought;
- (5) Identify the application to which it is directed;
- (6) State that the person making the oath or declaration has reviewed and understands the contents of the application, including the claims, as amended by any amendment specifically referred to in the oath or declaration;
- (7) State that the person making the oath or declaration acknowledges the duty to disclose to the Office all information known to the person to be material to patentability as defined in § 1.56;
- (8) Identify the mailing address, and the residence if an inventor lives at a location which is different from where the inventor customarily receives mail, of each inventor; and
- (9) Identify any foreign application for patent (or inventor's certificate) for which a claim for priority is made pursuant to § 1.55, and any foreign application having a filing date before that of the application on which priority is claimed, by specifying the application number, country, day, month, and year of its filing.

The Original Declaration filed in the present application satisfies each of these 9 requirements under § 1.63(a)-(c).

- (1) The Original Declaration includes a warning concerning willful false statements and sets forth that all statements are true or believed to be true.
- (2) Each inventor is identified by full name.
- (3) The country of citizenship of each inventor is identified.
- (4) Each person making the declaration states that they believe the named inventors to be the original and first inventor or inventors of the subject matter which is claimed and for which a patent is sought.
- (5) The application to which the Original Declaration is directed is accurately identified. (See remarks below in Section II.B).
- (6) The persons making the declaration state that they have reviewed and understand the contents of the application.
- (7) The persons making declaration acknowledge the duty to disclose as defined in § 1.56.
- (8) The mailing address of each inventor is listed.
- (9) No foreign application data is listed in the Original Declaration because the present application does not claim priority to any foreign application.

B) The Original Declaration Sufficiently Identifies The Application to Which It Is Associated as Required by 37 C.F.R. § 1.63(b)(1)

Section 1.63(b)(1) requires a declaration to "identify the application to which it is directed." Guidance as to information that satisfies the identification requirement is given in MPEP 602.VI. This section states that a declaration including the names of the inventors, title of the invention, application number, filing date, and foreign priority application information satisfies the identification requirement under § 1.63(b)(1). However, "it is not essential that all of [this information] be completed in order to adequately identify the specification in compliance with 37 C.F.R. § 1.63(b)(1)." MPEP 602.VI.

The following combinations of information supplied in a declaration filed on the application filing date are listed as acceptable minimums for identifying a specification in compliance with the identification requirement § 1.63(b)(1):

- (A) name of inventor(s), and reference to an attached specification which is both attached to the oath or declaration at the time of execution and submitted with the oath or declaration on filing;
- (B) name of inventor(s), and attorney docket number which was on the specification as filed; or
- (C) name of inventor(s), and title of the invention which was on the specification as filed.

MPEP 602.VI.

Because the present application (10/611,741) is a divisional application of application number 09/799,317, now US Patent 6,613,801, the Original declaration filed in the present application is a copy of the executed declaration filed in the prior application as allowed in § 1.63(d). The Original Declaration includes all suggested combinations of information to comply with the identification requirement under § 1.63(b)(1). The Original Declaration includes the names of the inventors, title of the invention, the application number (*i.e.*, the prior application number 09/799,317), and the filing date (*i.e.*, the prior application filing date March 5, 2001).

C) Domestic Priority Information In A Declaration In Not Required by § 1.63.

As previously stated, the Original Declaration filed in the present application inaccurately lists application number 60/346,125 from which the present application claims the benefit of domestic priority. The priority application number that should be listed is 60/207,343, as recited in the amended Statement of Related Applications filed at the same time as the Original Declaration and the present application.

Domestic priority information under 35 U.S.C. § 119(e) is not required by Rule 1.63 to complete a declaration. Further, MPEP 602.VI does not suggest that domestic priority information is useful to satisfy the identification requirement under Rule 1.63(b)(1). Indeed, the USPTO declaration form (PTO/SB/01 (04-05)) does not require or include a field to include domestic priority information under 35 U.S.C. § 119(e).

Applicants submit that the Original Declaration filed in the present application complies with the rules under § 1.63 and specifically in the information required by § 1.63(b)(1), and therefore the Original Declaration is not defective. Applicants respectfully request that the Examiner withdraw the requirement to submit a supplemental declaration in the present application under 37 C.F.R. § 1.67.

III. Inaccurate Domestic Priority Information in the Original Declaration Can Be Corrected by Supplemental Application Data Sheet

As described in 37 C.F.R. § 1.76(a), an application data sheet may be voluntarily submitted and contains bibliographic data, arranged in a format specified by the Office. The bibliographic data includes domestic priority information, such as the application number, the filing date, the status (including patent number if available), and relationship of each application for which a benefit is claimed under 35 U.S.C. § 119(e), 120, 121, or 365(c).

While the domestic priority information for the present application was accurately listed in the amended Statement of Related Applications filed in the preliminary amendment of July 1, 2003 and is now updated in this response (see page 2), Applicants herein attach a supplemental application data sheet with the present

response to correct the inaccurate domestic priority information listed in the Original Declaration.¹

As stated in the 37 C.F.R. § 1.76(c), supplemental application data sheets may be supplied prior to payment of the issue fee to correct or update information in:

a previously submitted . . . declaration under § 1.63 . . . , except that inventorship changes are governed by § 1.48, correspondence changes are governed by § 1.33(a), and citizenship changes are governed by § 1.63 or § 1.67.

37 C.F.R. § 1.76(c) (Emphasis Added).

Further, as stated in § 1.76(d)(1), for inconsistencies between information that is supplied by both an application data sheet and by a declaration under § 1.63, the latest submitted information will govern notwithstanding whether supplied by an application data sheet, or by a § 1.63 declaration, except as provided by § 1.76(d)(3).²

Because domestic priority information is not the type of information that must be corrected in a supplemental declaration under §1.67, Applicants respectfully request that the attached supplemental application data sheet be entered and accepted to correct the inaccurate domestic priority information listed in the Original Declaration.

IV. Conclusion

Without conceding or acquiescing to any of the conclusions in the decision on Applicants' petition mailed on July 11, 2005 or waiving the right to file a renewed

¹ Two of the inventors' mailing addresses are also updated: Wysong and Patron.

² Under § 1.76(d)(3), the oath or declaration under § 1.63 governs inconsistencies with the application data sheet in the naming of inventors and setting forth their citizenship.

petition within the statutory period, Applicants submit that the Original Declaration is not defective.

Applicants respectfully request that the Examiner withdraw the requirement to file a supplemental declaration under 37 C.F.R. § 1.67, and that the Examiner accept the attached supplemental data sheet to correct the inaccurate domestic priority information listed in the Original Declaration.

FEES

This complete response is being timely filed within the shortened statutory period of 3 months of the mailing of the Office Action on July 28, 2005. No additional fee is believed due, however, should a fee be deemed to be necessary, the Commissioner is hereby authorized to charge any fees required by this action or any future action to Deposit Account No. 50-3216.

Favorable consideration and allowance of the application are respectfully requested.

Should the Examiner believe that anything further is necessary to place the application in a condition for allowance, the Examiner is invited to contact the undersigned attorney at the telephone number listed below.

Respectfully submitted,

Date: Sept 20, 2005


Samuel B. Rollins
Reg. No. 52,180

TransTech Pharma, Inc.
4170 Mendenhall Oaks Pkwy
High Point, NC 27265
Ph: 336-841-0300 ext. 159
Fax: 366-841-0310